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**ATTACHMENT A**

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-21-

Serial No. 09/920,425

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**RECEIVED**  
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FEB 19 2004

Applicant(s): Bruce B. Lee

Assignee: BEKL Corporation

Title: GYNECOLOGICAL ABLATION PROCEDURE AND SYSTEM  
USING AN ABLATION NEEDLE

Serial No.: 09/920,425

Filing Date: July 31, 2001

Examiner: Peter J. Vrettakos

Group Art Unit: 3739

Docket No.: M-11515 US

**OFFICIAL**Irvine, California  
February 17, 2004COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450**DECLARATION OF DR. BRUCE B. LEE**  
**UNDER RULE 1.132**

I, Dr. Bruce B. Lee, declare as follows:

1. I am the inventor of the present invention claimed in U.S. Patent Application No. 09/920,425 and President of BEKL Corporation, the assignee of the aforementioned patent application, since formation of BEKL Corporation in 2000.

2. I received a Bachelor of Science degree in biology from the University of California at San Diego in 1976, and a Medical Doctorate degree from the University of Southern California in 1981, completing residency in obstetrics/gynecology at Los Angeles County/USC Medical Center in 1985. I have been employed as a practicing physician for the last 18 years in the field of obstetrics/gynecology, now specializing in gynecology.

3. I am the named inventor in the above-referenced patent application and am familiar with the application, as well as the development and usage of fibroid ablation techniques and systems.

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-22-

Serial No. 09/920,425

### BACKGROUND INFORMATION

4. Myolysis is the medical term for destruction of muscle cells. In one example in the application referenced above, the term refers to the destruction of a muscle cell tumor, or fibroid, which occurs in the smooth muscle of the uterus.

5. Two quite different methods to carry out myolysis include direct ablation of a tumor and indirect tumor treatment via ablation of a tumor's blood supply. Direct ablation of a tumor causes no harm or minimal harm to surrounding tissue. Indirect tumor treatment via ablation of a tumor's blood supply results in contact with normal tissue outside of the tumor and greatly increases the likelihood of severe complications, including uterine rupture. Thus, the two procedures are quite different methods in view of each other to one of ordinary skill in the art at the time of the present invention.

6. Ablation of the tumor mass itself with a prior art monopolar or bipolar needle system has inherent difficulties. Since the shape of the ablation zone with prior mono or bipolar systems is oval, cylindrical, or planar, and since fibroids are most often spherical, effective ablation of fibroids requires multiple and possibly numerous passes. This results in significant destruction of surrounding tissue and is time consuming.

7. Targeting the tumor's blood supply follows a completely different technique of using the needles to ring the tumor with coagulation, but also leads to potential problems of destroying healthy surrounding tissue.

8. To the best of my recollection, myolysis has been performed using bipolar cautery in this country since the late 1980's. The device most often used for this procedure has been a two-pronged needle electrode that used bipolar cautery. The technique included: inserting the device at the periphery of a visible fibroid tumor; activating the cautery, thus destroying the tissue between the electrodes; removing and reinserting the electrode, advancing serially around the tumor's circumference. This procedure was designed to interrupt the blood supply to the tumor.

9. However, this technique has several drawbacks. The normal surrounding muscle and the overlying serosa (thin, protective membrane over the uterus) incurs significant damage

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-23-

Serial No. 09/920,425

resulting in significant adhesion (scar) formation as noted postoperatively. Tumors not visible from the surface were not treated. Inconsistent, sub-optimal symptom relief and tumor shrinkage were observed following these procedures. In several cases, women who became pregnant after undergoing prior art procedures experienced uterine rupture and fetal loss as a result of damage to and lack of integrity of the uterine wall.

### THE PRESENT INVENTION

10. The present invention of utilizing radiofrequency ablation with a plurality of electrodes in combination with a laparoscope and a separate intra-abdominal ultrasound device disclosed in the above-referenced application is a novel and nonobvious way of performing myolysis. It treats essentially only the tumor itself, is not traumatic to the normal surrounding muscle, causes minimal damage to the serosa, and brings about rapid resolution of symptoms and return to normal activity in about 95% of cases.

11. The present invention has been made possible by the addition of several technical advances to laparoscopy: 1) the creation of electrodes capable of entering and ablating a defined area of variable and predictable size with appropriate ablation volume/shape for treating fibroids; and 2) the use of an intra-abdominal ultrasound device separate from the ablation device such that the uterus may be manipulated and stabilized during needle insertion. A separate intra-abdominal ultrasound device also allows for viewing in multiple planes to accurately check for proper needle insertion.

12. If an intra-abdominal ultrasound device was attached to the ablation device, the uterus could not be stabilized during needle insertion nor could multiple planes be viewed for accurate needle insertion. In other words, the ablation device and the uterus manipulating device, such as an intra-abdominal ultrasound probe, must be capable of being operated independent of the other.

13. Intra-abdominal ultrasound has resulted in the ability to detect and target tumors not previously visible with laparoscopy (i.e., looking inside the abdomen with a "scope"). This in turn has resulted in the ability to treat tumors regardless of location, size, and/or number. To the best of my knowledge, intra-abdominal ultrasound has not been previously applied to gynecologic conditions.

14. To the best of my knowledge, no other form of myolysis is as versatile and effective as in the present invention. The results of this new system and procedure have never been approached by other means of myolysis, or equaled by any other conservative therapy.

#### **LICENSE AGREEMENT BETWEEN RITA MEDICAL AND BEKL CORPORATION**

15. Rita Medical Systems, Inc. (hereinafter "Rita Medical"), assignee of the Edwards reference, as early as 2000, fully appreciated and had an interest and desire in Applicant's system and method for ablation of fibroids with minimal damage to surrounding healthy tissue.

16. The gynecological ablation procedure and system set forth in United States Patent Application No. 09/920,425 came to the attention of Rita Medical, who was sufficiently confident in the procedure and system outlined in the above-referenced patent application that they entered into negotiations for a License Agreement with BEKL Corporation. The License Agreement included payment for data, payment for foreign prosecution of the present invention in Europe, Japan, Korea, and Canada, long term royalties on sales of a new needle to be developed for ablation of uterine fibroids, and payment for instruction regarding the present invention.

17. I am in current negotiations with two other medical device companies to commercialize the present invention.

#### **COMMERCIAL SUCCESS**

18. The present invention has enjoyed substantial commercial success since its introduction and is expected to continue to do so. Using the method and system of the present invention, I have successfully carried out 150 operations to date resulting in relief of symptoms in more than 95% of cases.

19. To the best of my knowledge, no physicians in the United States are currently carrying out the method or using the system of the present invention.

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-25-

Serial No. 09/920,425

20. To the best of my knowledge, only two other physicians outside of the United States, one in Canada and another in Italy, have utilized intra-abdominal ultrasound to carry out direct uterine fibroid ablation after I pioneered the method. I know of no other doctor who has carried out as many operations as I have to ablate uterine fibroids and with as much success.

21. In my opinion, the commercial success I have enjoyed is an indication that the combination of elements in the ablation method and system of the present invention is nonobvious and should have relevancy as indicia of nonobviousness of the present invention.

### THE SAVAGE AND BEHL REFERENCES

22. In my opinion, U.S. Patent No. 5,979,453 to Savage et al. (hereinafter "Savage") discloses the use of a needle system and method to target a tumor's blood supply with minimal damage to the normal healthy tissue surrounding the tumor. The technique to target a tumor's blood supply, as disclosed in Savage, column 1, lines 43-50, causes damage to the normal surrounding muscle and tissue. Savage discloses no motivation to use more than a pair of electrodes to target the blood supply and instead teaches away because more needles would be less precise while causing more damage to surrounding healthy tissue.

23. The ultrasound transducer disclosed in Savage cannot be used to manipulate a bodily organ so as to position and stabilize the organ during needle insertion because the ultrasound transducer is directly connected to the distal end of the needle. (Savage, col.3, ll.62-65; FIG. 1).

24. The ultrasound transducer disclosed in Savage cannot be used to view multiple planes during needle insertion and is thus a significant disadvantage in regard to monitoring for electrode placement.

25. In my opinion, U.S. Patent No. 6,212,433 to Behl discloses that deployed electrodes are placed in tissue adjacent the tumor to necrose a boundary region and thereby inhibit blood flow. Behl is directed toward the ablation of cancerous tissue and is therefore less concerned with prevention of harm to surrounding tissue as a certain boundary around the cancerous mass is usually ablated.

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-26-

Serial No. 09/920,425

26. Combining the teachings of Savage with the plurality of electrodes disclosed in Behl is not proper as such a combination would destroy the intent and purpose of Savage to reduce damage to surrounding healthy tissue.

27. Even if Savage were modified by Behl, such a combination still targets the blood supply of a tumor by heating tissue adjacent a tumor with a plurality of electrodes. Accordingly, Savage in view of Behl still teaches away from insertion of the electrode completely within the tumor, as claimed in the present invention.

#### THE EDWARDS REFERENCE

28. In my opinion, U.S. Patent No. 5,935,123 to Edwards et al. (hereinafter "Edwards") only discloses a single electrode for targeting the bulk of the tumor itself. Edwards does not disclose or suggest targeting a tumor's blood supply or a peripheral area adjacent the tumor to target the blood supply. Edwards is not properly combinable with Savage and Behl because such a combination destroys the intent, purpose, and function of Savage and Behl to target the blood supply of the tumor, which requires heating of tissue adjacent the tumor as taught in Savage and Behl. Thus, Savage modified in view of Behl is not properly combinable with Edwards to show insertion of electrodes completely within the tumor because such a combination would destroy the purpose and function of Savage and Behl.

29. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that the statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above application and any patent issued thereon.

*Bruce B. Lee*

Dr. Bruce B. Lee

*2/19/04*

Date

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-26-

Serial No. 09, 20,425